UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

RICHARD LORETO, *et al.*,	:	Case No. 1:09-cv-815
Plaintiffs,	:	Judge Timothy S. Black
vs.	:	
THE PROCTER & GAMBLE CO.,	:	
Defendant.	:	

DECISION AND ENTRY GRANTING DEFENDANT'S MOTION TO DISMISS (Doc. 29)

This civil action is before the Court on the Motion to Dismiss (Doc. 29) filed by Defendant, the Procter & Gamble Company ("P&G"). P&G contends that the Consolidated Amended Class Action Complaint (Doc. 22) (the "Complaint") fails to state a claim upon which relief can be granted. P&G's position is that Plaintiffs assert claims under the Food, Drug & Cosmetics Act, 21 U.S.C. §§ 301, *et seq*. ("FDCA") for which no private right of action exists. Alternatively, P&G argues that Plaintiffs lack standing to assert claims under state consumer protection statutes in states where they do not reside. Further, P&G argues that the Complaint is devoid of factual allegations supporting the necessary elements of the claims asserted.

Plaintiffs filed a Response in Opposition to P&G's Motion to Dismiss. (Doc. 30). Defendant filed a Reply in Support of the Motion to Dismiss. (Doc. 31). This matter is now ripe for decision.

I. STANDARD OF REVIEW

A. Rule 12(b)(6)

A motion to dismiss pursuant to Rule 12(b)(6) operates to test the sufficiency of the complaint. Rule 12(b)(6) permits dismissal of a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). The complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). The plaintiff's ground for relief must entail more than "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

The first step in testing the sufficiency of the complaint is to identify any conclusory allegations. *Ashcroft v. Iqbal*, --- U.S. ---, 129 S. Ct. 1937, 1950 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 1949 (citing *Twombly*, 550 U.S. at 555). That is, "a plaintiff's obligation to provide the grounds of [his] entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly,* 550 U.S. at 555. Although the court must accept well-pleaded factual allegations of the complaint as true for purposes of a motion to dismiss, the court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Id.*

After assuming the veracity of all well-pleaded factual allegations, the second step is for the court to determine whether the complaint pleads "a claim to relief that is

plausible on its face." *Iqbal*, 129 S. Ct. at 1949, 1950 (citing *Twombly*, 550 U.S. at 556, 570). A claim is facially plausible when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 1949 (citing *Twombly*, 550 U.S. at 556).

In considering a motion under Fed. R. Civ. P. 12(b)(6), matters outside the pleadings should generally not be considered without converting the motion to one for summary judgment under Fed. R. Civ. P. 56. *See Smith v. Potter*, No. 1:08-cv-390, 2009 U.S. Dist. LEXIS 61827, at *14-15 (S.D. Ohio Jun. 29, 2009). There are, however, exceptions to this general rule. *Id.*

As in this case, "documents whose contents are alleged in a complaint and whose authenticity is uncontested, but that are not physically attached to the pleading, may be considered in ruling on a Rule 12(b)(6) motion to dismiss[.]" *Plassman v. City of Wauseon*, 85 F.3d 629 (6th Cir. 1996) (citing *Branch v. Tunnell*, 14 F.3d 339 (9th Cir. 1994)); *see also In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1042 n.2 (stating that "a court ruling on a motion to dismiss may consider the full texts of documents which the complaint quotes only in part"); *Smith*, 2009 U.S. Dist. LEXIS 61827 at *15 (stating that "when a document is referred to in the pleadings and is integral to the claims, it may be considered without converting a motion to dismiss into one for summary judgment").

B. Rule 12(b)(1)

A motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) asserts that the court lacks subject-matter jurisdiction. Such a motion may consist of a "facial attack," under which

the moving party asserts that the allegations of the complaint are not sufficient to establish jurisdiction, or a "factual attack," under which the court may consider evidence to determine if jurisdiction does exist. *O'Bryan v. Holy See*, 556 F.3d 361, 376-77 (6th Cir. 2009).

In considering a factual attack, the court looks at evidence outside the pleadings, and "no presumptive truthfulness attaches to the plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *RMI Titanium Co. v. Westinghouse Elec. Corp.*, 78 F.3d 1125, 1134 (6th Cir. 1996). Moreover, even under a facial attack, conclusory allegations or legal conclusions masquerading as factual conclusions will not prevent dismissal. *O'Bryan*, 556 F.3d at 377.

II. NATURE OF THE CLAIMS

This action concerns two P&G products: (1) Vicks DayQuil Cold and Flu Symptom Relief Plus Vitamin C; and (2) Vicks NyQuil Cold and Flu Symptom Relief Plus Vitamin C (collectively referred to as the "Products"). (Doc. 22). According to the Complaint, the Products consist of a combination of vitamin C with the well-known DayQuil and NyQuil products. As Plaintiffs allege, P&G simply "added Vitamin C to both its Nyquil and Dayquil products." (*Id.*)

Plaintiffs, Richard Loreto and Larry Buffa, allege that P&G specifically developed the Products in an effort to capitalize on an allegedly common misconception that vitamin

C is useful for the treatment or prevention of the common cold.[1] (*Id.*) Plaintiffs contend that vitamin C is not effective in treating or preventing the common cold, and P&G's representations otherwise are false and misleading. (*Id.*) Plaintiffs allege that "had [they] been aware of the fact that [the Products] were not effective for their intended uses and that it was illegal for P&G to sell [the Products], Plaintiffs and members of the class would not have purchased the [P]roducts." (*Id.*) They further allege that "[t]hese representations were a substantial factor in causing Plaintiffs . . . to purchase" the Products "instead of lower priced competitors' products." (*Id.*)

Plaintiffs contend that P&G's false or misleading representations regarding the efficacy of the Products to prevent, treat or relieve the symptoms of the cold or flu violate state consumer statutes, specifically Ohio's Consumer Sales Practices Act ("OCSPA"), Ohio's Deceptive Trade Practices Act ("ODTPA"), the New Jersey Consumer Protection Act ("NJCPA"), and consumer statutes in all other states and the District of Columbia. (*Id.*) Plaintiffs also set forth a claim for unjust enrichment. (*Id.*)

Plaintiffs, both residents of New Jersey, assert these causes of action individually and also seek to represent a class "consisting of all persons in the United States who . . . purchased" the Products. (*Id.*) Plaintiff also seek to assert these claims on behalf of a subclass "consisting of all residents of New Jersey who . . . purchased" the Products. (*Id.*)

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[1] Plaintiffs also allege that the Products were developed and introduced to consumers in an effort to "capitalize on the [then] current swine flu hysteria by appealing to common consumer misconceptions regarding the efficacy of Vitamin C." (Doc. 22).

III. FACTUAL ALLEGATIONS

For purposes of this motion to dismiss, the Court must: (1) view the Complaint in the light most favorable to the Plaintiffs, and (2) take all well-pleaded factual allegations as true. *Tackett v. M&G Polymers*, 561 F.3d 478, 488 (6th Cir. 2009); *Gunasekera v. Irwin*, 551 F.3d 461, 466 (6th Cir. 2009).

Plaintiffs contend that P&G made false or misleading representations about the efficacy of the Products to prevent, treat or relieve the symptoms of the common cold or flu. (Doc. 22). Specifically, Plaintiffs point to P&G's marketing and promotion of the Products "for 'COLD & FLU Multi-Symptom Relief'" in a package bearing "a 'Drug Facts' panel stating that this product is to be used to 'temporarily relieve[ ] common cold/flu symptoms: • nasal congestion • cough due to minor throat and bronchial irritation • sore throat • headache • minor aches and pains [and] • fever.'" (*Id.*)

Plaintiffs further allege that P&G made the following false or misleading representations on the website www.vicks.com:

- Combining the powerful multi-symptom relief of DayQuil with more than 150% of the recommended value of vitamin C.

- VICKS NyQuil Cold & Flu Symptom Relief Plus Vitamin C provides multi-symptom cold and flu relief so you can get the sleep you need to enjoy an even sweeter tomorrow. Plus, you'll also replenish your body with 150% of the daily value of vitamin C.

- Fortify Your Household for the Cold and Flu Season. . . . Vitamin C: It won't cure a cold, but vitamin C can help blunt its effects. Aim for 500 mg a day.

- Fighting Cold and Flu Season. . . . Don't forget to take your daily vitamins. Consider taking extra vitamin C, vitamin A, and zinc, all of which may help you.

(*Id.*)

P&G also created print advertisements bearing the allegedly false or misleading tagline: "Treat the cold. Replenish the body." (*Id.*) These print advertisements further state: "New Vicks DayQuil Plus Vitamin C. Now you can get multi-symptom relief with DayQuil and help replenish your body with 150% of the daily value of vitamin C. For nighttime relief, try new Vicks NyQuil Plus Vitamin C." (*Id.*)

Finally, Plaintiffs point to a "television, Internet and print advertising campaign" which contained "a compilation of tips from America's favorite television moms, such as Florence Henderson, Shirley Jones and Meredith Baxter on how they care for their loved ones during the cold and flu season." (*Id.*) Of significance, Plaintiffs emphasize the following statements made by Marion Ross: "Now I'm especially excited because Vicks is bringing together DayQuil and NyQuil, to help relieve multiple cold symptoms, with Vitamin C to replenish what your body needs." (*Id.*) (emphasis in Complaint omitted).

To support the general allegations that these representations are false or misleading, the Complaint quotes a Warning Letter prepared by the Food and Drug Administration ("FDA") and issued to P&G in October 2009.[2] (*Id.*) The Warning Letter

[2] Because the FDA Warning Letter is quoted extensively in the Complaint, the contents of the Warning Letter will be considered in determining P&G's Motion to Dismiss. *Plassman*, 85 F.3d 629; *see also In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1042 fn 2; *Smith*, 2009 U.S. Dist. LEXIS 61827 at *15.

states that the FDA's "final monograph[3] [for over-the-counter ("OTC") cold-cough drugs] does not allow for the combination of vitamin C with any of the other active ingredients" in the Products. (*Id.*) As a result, the Products, as a combination of DayQuil/NyQuil with vitamin C, "do not comply with the final monograph for OTC Cold-Cough" drugs, and therefore, lack the FDA's recognition as safe and effective. (*Id.*) In order to obtain FDA recognition as safe and effective for intended use, and to properly sell the Products in interstate commerce, P&G was allegedly required to submit a "new drug" application and have it approved by the FDA, pursuant to 21 U.S.C. § 355(a). (*Id.*)

The FDA's omission of vitamin C from the final monograph for OTC cold-cough drugs is based on the recommendation of an Advisory Review Panel ("Panel") which, circa 1976, "reviewed the available data for [vitamin C] as a single entity and [found] that the data are insufficient to permit final classification as safe and effective for OTC use in the prevention or treatment of the cold." (*Id.*) Specifically, the Panel "found no study which demonstrated that vitamin C is unequivocally effective for the prevention or treatment of the 'common cold' although some data tended to favor effectiveness for treatment of cold symptoms." (*Id.*)

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[3] With regard to the term "final monograph" as used in the FDA's process of approving over-the-counter drugs, one court summarized the process as follows:

> First, the FDA appoints an advisory review panel of independent qualified experts. This panel submits a recommendation to the FDA stating whether a drug is or is not safe and effective for its designated purposes or whether there is insufficient evidence upon which to base a recommendation. Second, the FDA publishes a tentative "final monograph" presenting its initial position on the drug's safety and effectiveness. Third, after an extensive comment and review period, the FDA publishes a final monograph that establishes the conditions under which a drug is considered safe and effective. See 21 C.F.R. § 330.10 (1988). Once a final monograph goes into effect, it is illegal to sell a drug described therein unless it conforms therewith.

Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 226 (3rd Cir. 1990).

With regard to the use of vitamin C in combination with other OTC cold-cough drugs, the Panel found that vitamin C "combination products for the prevention of colds is irrational since other ingredients in these products should only be used when the symptoms of the 'common cold' are present." (*Id.*) Therefore, the Panel concluded that "[i]t would be illogical for a consumer to take a cold combination product to prevent a cold." (*Id.*)

Apparently based on the foregoing Panel findings, in 2002, the FDA stated the following with regard to vitamin C and the final monograph for OTC cold-cough drugs:

> The agency has determined that the submitted studies do not contain sufficient detail to assess their value in establishing the effectiveness of ascorbic acid [vitamin C] in reducing the duration or symptoms of the common cold. . . . Thus, the agency is not including ascorbic acid in this final monograph.

(*Id.*) In other words, the FDA does not generally recognize vitamin C as effective for use as an OTC cold-cough drug.

Notably, aside from vitamin C, the other ingredients in the Products, namely "acetaminophen and dextromethorphan HBr, along with phenylephrine HCI . . . or doxylamine succinate[,]" are recognized by the FDA to have "the intended uses of . . . pair reliever/fever reducer, cough suppressant, nasal decongestant, and antihistamine." Despite this recognition, because vitamin C is not included in the final monograph, its mere presence in the Products renders them "not generally recognized as safe and effective for their intended uses." (*Id.*) However, there is nothing in the Warning Letter

or otherwise alleged in the Complaint suggesting that the addition of vitamin C renders the other ingredients in the Products literally ineffective as "pair reliever/fever reducer, cough suppressant, nasal decongestant, and antihistamine[.]"

IV. LAW AND ANALYSIS

A. Applicable State Consumer Statutes

Initially, the Court will address P&G's assertion that the individually named Plaintiffs lack standing to pursue claims under any state consumer statute except that of New Jersey. Specifically, P&G contends that the Complaint simply alleges that Plaintiffs reside in New Jersey, and fails to otherwise allege any significant connection to any other state besides the fact that P&G is headquartered in Ohio. (Doc. 29). In their Memorandum in Opposition to P&G's Motion to Dismiss (Doc. 30), Plaintiffs admit that the only alleged connection to Ohio is the fact that P&G is headquartered in Ohio.

Plaintiffs contend that, regardless of their individual standing to assert claims under all state statutes, they seek to represent a class that, if certified, may have standing under those state statutes. (Doc. 30). In support of their contention, Plaintiffs' cite *In re Bayer Corp. Combination Aspirin Prods. Mktg. and Sales Practices Litig.*, 701 F. Supp. 2d 356, 376-78 (E.D.N.Y 2010), wherein the court denied a motion to dismiss class "claims brought under the laws of states other than those in which the named plaintiffs reside and where each made their purchases." There, however, the court also determined that the named plaintiffs themselves sufficiently pled a cause of action that survived a motion to dismiss. *Id.*

Generally, "[t]o maintain a class action, 'a named plaintiff [must have] a [live] case or controversy at the time the complaint is filed and at the time the class action is certified.'" *Gawry v. Countrywide Home Loans, Inc.*, 640 F. Supp. 2d 942, 950 (N.D. Ohio 2009). If the named Plaintiffs in this case do not properly assert a cause of action on their own behalf, they cannot represent the proposed classes. *Id.*

Therefore, for purposes of determining this Motion to Dismiss, the Court will first focus on whether the named Plaintiffs state a claim under their respective state's consumer statute, *i.e.*, the NJCPA. S*ee Suarez v. Playtex Products, Inc.*, Nos. 08 C 2703, 08 C 3352, 2009 WL 2212315, at *2 (N.D. Ill. Jul. 24, 2009) (stating that because the individually named plaintiffs "are residents of New York and California, respectively, and neither alleges injury in, or contact with, any other jurisdiction . . .Plaintiffs' claims . . . based on the consumer protection statutes of jurisdictions other than New York and California must therefore be dismissed for failure to state a claim").

With regard to claims asserted under Ohio statutes, this District previously found that claims asserted under the OCSPA "asserted on behalf of proposed class members whose purchase of . . . [the subject product] did not take place in Ohio [is] barred by the jurisdictional provision of the statute." *Delahunt v. Cytodyne Technologies*, 241 F. Supp. 2d 827, 839 (S.D. Ohio 2003); Ohio Rev. Code Ann. § 1345.04. More recently, the U.S. District Court for the Northern District of Ohio, in determining the applicability of the OCSPA to out of state residents based simply on the assertion that allegedly offending advertisements emanated "from Ohio," stated:

> It is undisputed that the place of injury for these actions is the home state of the individual class members. Plaintiffs' sole argument on this issue consists of the fact that the advertisements and website at issue emanate from Ohio, UHC's principle place of business. Standing alone, this is insufficient to apply Ohio law to a nationwide class for several reasons. First, Ohio courts have found that the OSCPA cannot apply to consumers outside the state of Ohio. *See Chesnut v. Progressive Cas. Ins. Co.*, 166 Ohio App.3d 299, 305-06, 850 N.E.2d 751 (2006) (rejecting a claim that the OSCPA should apply because "Progressive is headquartered in Ohio [and] the policies and procedures [at issue] emanate from Ohio"); *see also Delahunt v. Cytodyne*, 241 F. Supp.2d 827 (S.D. Ohio 2003) (striking claims sought to be brought on behalf of consumers that did not purchase the suspect product within the state of Ohio).

Pilgrim v. Universal Health Card, LLC, No. 5:09cv879, 2010 WL 1254849, at *3-4 (N.D. Ohio Mar. 25, 2010). Based on the foregoing, the individually named Plaintiffs have no standing to pursue claims under the OCSPA or the ODTPA.

B. Claims Under the New Jersey Consumer Protection Act

As residents of New Jersey, the individually named Plaintiffs assert a claim under the New Jersey Consumer Protection Act ("NJCPA"). Under this claim, Plaintiffs contend that P&G engaged in unlawful actions under the NJCPA by falsely or misleadingly representing that the Products were effective in preventing or treating the cold or flu. (Docs. 22, 30). Plaintiffs allege they were damaged because they paid for the Products "to treat conditions for which the drugs were not efficacious, effective and useful." (Doc. 22). Plaintiffs contend that their reliance on such representations caused them to purchase the Products "instead of lower priced competitors' products." (*Id.*)

Plaintiff do not allege, however, that the Products, as a whole, actually failed to treat the symptoms of their cold or flu.[4]

The NJCPA "imposes liability on any person who uses: 'any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission.'" *Int'l Union of Operating Engineers Local 68 Welfare Fund v. Merck & Co., Inc.*, 192 N.J. 372, 929 A.2d 1076, 1086 (2007) (quoting N.J.S.A. 56:8-2). Violations of the NJCPA "are divided broadly 'into three ... categories: affirmative acts, knowing omissions, and regulatory violations.'" *Id.* (citing *Cox v. Sears Roebuck & Co.*, 138 N.J. 2, 647 A.2d 454 (1994)). Here, Plaintiffs' claims fall within the "affirmative acts" category.

The NJCPA provides a private right of action for "[a]ny person who suffers ascertainable loss of moneys or property, real or personal, as a result of the . . . of any method, act, or practice declared unlawful under this act[.]" N.J.S.A. 56:8-19. As a result, in order to properly state a claim under the NJCPA, "a plaintiff must allege 'three elements: (1) unlawful conduct . . .; (2) an ascertainable loss . . .; and (3) a causal relationship between the defendants' unlawful conduct and the plaintiff's ascertainable loss.'" *Int'l Union*, 929 A.2d at 1086 (citing *N.J. Citizen Action v. Schering-Plough*

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[4] To the contrary, the allegations of the Complaint, which quote the FDA's Warning Letter, recognize that the active ingredients in the regular DayQuil and NyQuil products without vitamin C have "the intended uses of . . . pain reliever/fever reducer, cough suppressant, nasal decongestant, and antihistamine[.]" (*Id.*) There is nothing in the Warning Letter indicating that the mere addition of vitamin C renders these other active ingredients literally ineffective as a "pain reliever/fever reducer, cough suppressant, nasal decongestant, and antihistamine[,]" and Plaintiffs have not alleged as much.

Corp., 367 N.J.Super. 8, 842 A.2d 174 (App.Div.), cert. denied, 178 N.J. 249, 837 A.2d 1092 (2003)).

In moving to dismiss the Complaint, P&G first contends that despite the fact that Plaintiffs present their cause of action in the form of a claim under the NJCPA (and other state consumer protection statutes), such cause of action is, in actual substance, an improper attempt to assert a private right of action under the FDCA. Next, P&G argues that, even assuming that Plaintiffs' claim is not an improper attempt to assert a private right of action under the FDCA, the NJCPA claim (and any claim under any other state consumer protection law) must be dismissed because Plaintiffs allege no actual injury, fail to allege causation, and otherwise fail to allege other essential elements of the individual state consumer law causes of action.

C. Private Right of Action Under the Food, Drug & Cosmetics Act

P&G argues that the claims asserted in the Complaint are all claims seeking to privately enforce the provisions of the FDCA, for which no private right of action exists. Pursuant to 21 U.S.C. § 337(a), absent specifically delineated exceptions not applicable in this case, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."

Courts interpret 21 U.S.C. § 337(a) to restrict enforcement of the FDCA to the FDA, and that "no private cause of action exists for a violation of the FDCA." *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000); *Bailey v. Johnson*, 48 F.3d 965 (6th Cir. 1995); *Iams Co. v. Nutro Products, Inc.*, No. C-3-00-566, 2004 WL 5780000, *1

(S.D. Ohio Jul. 19, 2004); *see also In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1287 (C.D. Cal. 2008) (stating that " no private right of action exists to redress alleged violations of the FDCA"); *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3rd Cir. 1990); *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130 (4th Cir. 1993).

The absence of a private right of action to enforce the FDCA means that not only is a private party precluded from bringing suit to enforce the provisions of the FDCA, they also "may not use other federal statutes or state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA." *In re Epogen*, 590 F. Supp. 2d at 1290-1291. A purported state-law claim does not exist where the "claim is in substance (even if not in form) a claim for violating the FDCA - that is, when the state claim would not exist if the FDCA did not exist." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009). Simply put, "plaintiff must not be suing because the conduct violates the FDCA[.]" *Id.*

This does not mean, however, that state law claims are completely precluded simply because the conduct violates the FDCA. *See Iams Co.*, 2004 WL 5780000 at * 3. State and federal laws "remain in effect to protect consumers from false and deceptive . . . advertising." *In re Epogen*, 590 F.Supp.2d. at 1290; *see also Iams Co.*, 2004 WL 5780000 at * 3. This is true because "the main purpose of the advertising restrictions set forth in the FDCA and its accompanying regulations is not to protect consumers from deceptive advertising, but rather to further the FDCA's underlying goal of ensuring the

safety of prescription drugs." *Id.* at 1290; *see also Iams Co.*, 2004 WL 5780000 at * 2 (stating that "the FD&C Act . . . is not focused on the truth or falsity of advertising claims"). Thus, "insofar as Plaintiffs can identify specific representations by Defendants that are literally false, misleading, or contain material omissions, the claims are actionable under . . . [state] consumer fraud laws." *Id.* at 1292.

Here, the entirety of the claims in the Complaint rely on allegations that P&G falsely and misleadingly represented that the Products were effective for treatment of the common cold or flu.[5] In support of their assertion that their state consumer claims based on false or misleading representations are not pre-empted by the FDCA, Plaintiffs largely rely on *Bayer*, 701 F. Supp. 2d 356, which also concerned two combination OTC drug products (low-dose aspirin plus calcium and low-dose aspirin plus phytosterols).

In *Bayer*, plaintiffs alleged that the drug company "misrepresented the safety and efficiency of the combination products" because consumers using the product as part of a low-dose aspirin regimen could not get the recommended daily dose of calcium or phytosterols without dangerously exceeding the daily recommended dose of aspirin.[6] *Id.*

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[5] This is exactly how Plaintiffs themselves characterize their claims, stating that "the 'substance' of Plaintiffs' Complaint is that P&G made misrepresentations to them about the efficacy of vitamin C, and combination DayQuil and NyQuil products containing vitamin C, for the treatment and prevention of the cold and flu." (Doc. 30). While the Complaint quotes statements by the FDA regarding "false and misleading" labeling, such statements concern alleged FDA misbranding violations regarding the listing of "active" and "inactive" ingredients in the Products. It is readily apparent from a reading the Complaint (Doc. 22), in its entirety, and Plaintiffs' Memorandum in Opposition (Doc. 30), that Plaintiffs' claims are not based on alleged "misbranding" violations. Insofar as the Complaint attempts assert a claim based on alleged "misbranding," there is no private right of action. *See Sandoz*, 902 F.2d at 230-233 (holding that "the issue of whether an ingredient is properly labeled as 'active' or 'inactive' under FDA standards is not properly decided as an original matter by a district court").

[6] Specifically, plaintiffs in *Bayer* alleged that "the combination products were advertised as appropriate for long-term use even though they were not; Bayer Calcium was advertised as a source of calcium even though it was not; and Heart Advantage was marketed as reducing cholesterol and providing cardiovascular benefits even though someone taking one tablet a day as part of a low-dose aspirin regimen would only ingest half the recommended amount of phytosterols." *Id.* at 375.

at *373-76. Thus, plaintiffs' claims were not premised solely on the FDA's determination that the drugs were inefficient for their proposed use, but rather because the combination products were not, in fact, a sufficient source of calcium or phytosterol, contrary to representations by Bayer. *Id.*

The court in *Bayer* found that plaintiffs' claims were viable outside the FDCA, despite the fact that they "touch on areas regulated by the FDA, and may even require reference to FDA definitions as to what the requirements are for adequate sources of calcium and phytosterols and what the dangers of larger doses of aspirin are[.]" *Id.* at 375. Thus, the court concluded: "plaintiffs have threaded the needle and alleged conduct that violates the FDCA but sounds in traditional principles of state law and would give rise to recovery even had the FDCA never been enacted." *Id.*

In this case, similarly to *Bayer*, Plaintiffs generally allege that P&G made false representations or mislead consumers by creating the false impression that the Products were "effective for their intended uses" of providing multi-symptom cold and flu relief. (Doc. 22). However, unlike *Bayer*, Plaintiffs' factual allegations of falsity in this case do not extend beyond the FDA's determination of ineffectiveness.

Generally, to prevail on a claim that defendant misrepresented the effectiveness of its product, plaintiffs must show that the alleged misrepresentations are "false or misleading, not merely that [they] are unsubstantiated by acceptable tests or other proof." *Sandoz Pharm. Corp.*, 902 F.2d at 228 (quoting *Bristol-Myers Co. v. F.T.C.*, 738 F.2d

554, 562 (2nd Cir.1984)).[7] In other words, "there is a clear and decisive difference between allegations that actually contest the safety and effectiveness of the Subject Drugs and claims that merely recite violations of the FDCA, for which there is no private right of action." *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2009 U.S. Dist. LEXIS 58900, at * 47 (D. N.J. Jul. 10, 2009). Here, Plaintiffs merely recite FDA determinations and alleged violations of the FDCA and do not set forth factual allegations actually contesting the "safety and effectiveness" of the Products. *Id.*

To support their assertion that P&G's apparent representations regarding the effectiveness of the Products are false, Plaintiffs' quote the FDA Warning Letter, which itself quotes recommendations from an FDA Panel finding:

> no study which demonstrated that vitamin C is unequivocally effective for the prevention or treatment of the "common cold" although some data tended to favor effectiveness for treatment of cold symptoms. Since no conclusive data on the dose or dosage schedule are available on vitamin C used alone or in combination products with other ingredients for prevention or treatment of the cold, the Panel is unable to propose adequate labeling with a dosage regimen . . .

(Doc. 22). Even viewing this passage in a light most favorable to Plaintiffs fails to result

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[7] Notably, the court in *Sandoz* applied this holding to claims asserted pursuant to the federal Lanham Act. The Ohio Deceptive Trade Practices Act, which Plaintiffs' assert a cause of action, "is substantially similar to the federal Lanham Act[.]" *Dawson v. Blockbuster, Inc.*, No. 86451, 2006 WL 1061769 (Ohio Ct. App. Mar. 16, 2006) (citing *Yocono's Restaurant, Inc. v. Yocono*, 100 Ohio App.3d 11, 17, 651 N.E.2d 1347 (1994)). "When adjudicating claims under the Ohio Deceptive Trade Practices Act, Ohio courts shall apply the same analysis applicable to claims commenced under analogous federal law." *Id.* (citing *Chandler & Assoc. v. America's Healthcare Alliance*, 125 Ohio App.3d 572, 579, 709 N.E.2d 190 (1997)). Therefore, even if Plaintiffs had sufficient standing to assert claims under Ohio's Deceptive Trade Practices Act, they must be dismissed as further set forth herein.

in the conclusion that vitamin C is actually ineffective in preventing, treating or relieving the symptoms of the common cold. To the contrary, the Panel recognized that "some data tended to favor [vitamin C's] effectiveness for treatment of cold symptoms" but an adequate dosing regimen could not be proposed. (*Id.*)

In 2002, the FDA stated the following with regard to the final monograph for OTC cold-cough drugs:

> The agency has determined that the submitted studies do not contain sufficient detail to assess their value in establishing the effectiveness of ascorbic acid in reducing the duration or symptoms of the common cold. . . . Thus, the agency is not including ascorbic acid in this final monograph.

(*Id.*) Again, as stated in the above quoted passage, the FDA's omission of vitamin C from the final monograph for OTC cold-cough drugs is not based on a literal finding that vitamin C is ineffective in preventing, treating or relieving the symptoms of the common cold.

Therefore, in reviewing the factual allegations in the Complaint as a whole, it is evident that Plaintiffs' allegations of false or misleading representations depend solely on the FDA's determination that the Products "are not generally recognized as safe and effective for their intended uses." (Doc. 22). The FDA's determination in this regard is not literal, instead, it is simply founded on the FDA's finding that "submitted studies do not contain sufficient detail to assess their value in establishing the effectiveness of ascorbic acid [vitamin C] in reducing the duration or symptoms of the common cold." (*Id.*); *see Sandoz Pharm. Corp.*, 902 F.2d at 228 (plaintiffs must show that the alleged

misrepresentations are "false or misleading, not merely that [they] are unsubstantiated by acceptable tests or other proof"). Further, the Panel's recommendations quoted in the Complaint actually reveal that "some data tended to favor [vitamin C's] effectiveness for treatment of cold symptoms." (Doc. 22).

Accordingly, because the substance of Plaintiffs' claims seek to assert a private right of action under the FDCA, they must be dismissed. *See In re Schering-Plough Corp.*, 2009 U.S. Dist. LEXIS 58900, at * 47 (stating that "there is a clear and decisive difference between allegations that actually contest the safety and effectiveness of the Subject Drugs and claims that merely recite violations of the FDCA, for which there is no private right of action"); *see also* 21 U.S.C. § 337(a).

Further, it must be noted that, beyond alleging the ineffectiveness of vitamin C in preventing or treating the cold or its symptoms, Plaintiffs assert that they would not have purchased the Products had they "been aware of the fact . . . that it was illegal for P&G to sell" the Products. (Doc. 22). After reviewing the Complaint as a whole, the Court concludes that this allegation is based on the determination in the FDA Warning Letter that "the current marketing of these two [P]roducts violates section 505(a) of the Act (21 U.S.C. § 355(a)), because they are new drugs and neither is subject of an approved new drug application." (Doc. 22).

In other words, Plaintiffs seek damages as a result of P&G's alleged failure to seek and obtain the FDA's approval before selling the Products in interstate commerce. No private right of action exists for such a claim, and insofar as Plaintiffs seek recovery for such alleged violations, those claims are dismissed. 21 U.S.C. § 337(a).

D. Ascertainable Loss Under the NJCFA and Unjust Enrichment

Alternatively, P&G argues that Plaintiffs have failed to allege any ascertainable loss, and, therefore, their NJCPA claim and their unjust enrichment claim must be dismissed even if a private right of action exists. To satisfy this essential element of an ascertainable loss, "a private plaintiff must produce evidence from which a factfinder could find or infer that the plaintiff suffered an actual loss." *Thiedemann v. Mercedes-Benz USA, LLC*, 183 N.J. 234, 872 A.2d 783, 792 (2005). "In cases involving . . . misrepresentation, either out-of-pocket loss or a demonstration of loss in value will suffice to meet the ascertainable loss hurdle and will set the stage for establishing the measure of damages." *Id.* Ascertainable loss must be supported by evidence and "presented with some certainty demonstrating that it is capable of calculation[.]" *Id.*

Courts have stated that a plaintiff must "specifically allege that what he did receive [ ] was of lesser value than what was promised[.]" *Arcand v. Brother Int'l Corp.*, 673 F. Supp. 2d 282, 301 (D.N.J. 2009) (citing *Solo v. Bed Bath & Beyond, Inc.*, No. 06-1908(SRC), 2007 WL 1237825 (D.N.J. Apr. 26, 2007). In so doing, plaintiff must typically "allege facts pertinent to their own personal experience with the product." *Id.* (citing *Franulovic v. Coca-Cola Co.*, No. 07-539(RMB), 2007 WL 3166953 (D.N.J. Oct. 25, 2007)). A consumer has not suffered ascertainable loss where that consumer gets what he/she paid for. *Arcand*, 673 F. Supp. 2d at 302.

Ascertainable loss is insufficiently plead where a plaintiff simply contends that the price charged for the misrepresented product "was higher than it should have been as a result of defendant's fraudulent marketing campaign[.]" *Int'l Union*, 929 A.2d at 1088. In the realm of "pharmaceutical products[,]" courts applying the NJCPA in conjunction with the FDCA have held that plaintiffs "have no private cause of action where they receive the benefit of the bargain in the form of effective drugs." *In re Schering-Plough*, 2009 U.S. Dist. LEXIS 58900 at *38-39.

Here, there are simply no allegations in the Complaint that Plaintiffs did not receive what they bargained for when they purchased the Products. To the contrary, Plaintiffs simply allege that P&G's representations caused them to purchase the Products "instead of lower priced competitors' products." (Doc. 22). In other words, there are no factual allegations contained anywhere in the Complaint asserting that the Products were actually ineffective in treating or relieving the symptoms of Plaintiffs' cold or flu. *Arcand*, 673 F.Supp.2d at 301 (stating that a plaintiff must "allege facts pertinent to their own personal experience with the product"); *see also Schering-Plough Corp.*, 2009 U.S. Dist. LEXIS 58900 at *47 (finding no actual injury where plaintiffs "have merely alleged that the Subject drugs were not FDA approved for certain conditions or that the relative effectiveness of the Subject Drugs had not been proven through conclusive evidence").

In fact, the allegations of the Complaint actually undermine Plaintiffs' general allegations regarding the efficacy of the Products to treat or relieve the symptoms of the cold or flu. Specifically, the Complaint quotes the FDA's recognition that active

ingredients present in the Products have "the intended uses of . . . pain reliever/fever reducer, cough suppressant, nasal decongestant, and antihistamine[.]" (Doc. 22). Nothing in the FDA Warning Letter or Plaintiffs' Complaint indicates or factually alleges that the addition of vitamin C renders these other active ingredients literally ineffective for those intended uses. Thus, Plaintiffs' purchased the Products for multi-symptom cold or flu relief, and they received products containing ingredients effective for the use of providing multi-symptom cold or flu relief, plus vitamin C.

Insofar as the Complaint could be read to allege that P&G represented that vitamin C provided some additional benefit, the Complaint still fails to allege that Plaintiffs did not receive any such represented benefit. The specifically cited statements by P&G, viewed in a light most favorable to Plaintiffs, represent that vitamin C "can help blunt" the effects of the common cold and that the Products provide in excess of the daily value of vitamin C. (*Id.*) There are no factual allegations contending that the vitamin C in the Products actually failed to blunt the effects of Plaintiffs' cold. In fact, the FDA Warning Letter quoted extensively throughout the Complaint states that "some data tended to favor effectiveness [of vitamin C] for treatment of cold symptoms." (*Id.*) Finally, there are no allegations that the Products failed to provide the represented amounts of vitamin C.

Accordingly, after reviewing the Complaint in a light most favorable to Plaintiffs, the Court can only reach the conclusion Plaintiffs received exactly what they bargained for in purchasing the Products. There is simply a lack of factual allegations to the contrary. As a result, Plaintiffs' unjust enrichment claim must be dismissed. *See In re*

Schering-Plouch Corp., 2009 U.S. Dist. LEXIS 58900 at *120-122 (dismissing claims for unjust enrichment under New Jersey law where plaintiffs failed to adequately plead ascertainable loss).

E. Dismissal With or Without Prejudice

Having determined that the Complaint must be dismissed as an improper attempt to assert a private right of action under the FDCA where no right exists, the final question is whether the Complaint should be dismissed with or without prejudice, or whether Plaintiffs should be given another opportunity to attempt to cure the pleading deficiencies. District courts have discretion in determining whether to dismiss a complaint with prejudice or to allow plaintiff the opportunity to amend the complaint. *See U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 342 F.3d 634, 644 (6th Cir. 2003).

In cases "where a more carefully drafted complaint might state a claim, a plaintiff must be given at least one chance to amend the complaint before the district court dismisses the action with prejudice." *Id.* (citing *EEOC v. Ohio Edison Co.*, 7 F.3d 541, 546 (6th Cir.1993)). However, denial for further amendments to the complaint "may be appropriate . . . where there is ' . . . repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc.'" *Id.* (citing *Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir.2002) (quoting *Foman v. Davis*, 371 U.S. 178 (1962))). Where previous amendments were allowed, a court need not *sua sponte* allow further opportunities to amend where no further attempt to amend the complaint is sought. *Simon v. Belwith Int'l Inc.*, 3 Fed. Appx. 363, 365 (6th Cir. 2001).

Here, Plaintiff Loreto filed his original Complaint (Doc. 1) on November 4, 2009. (Doc. 1). Plaintiff Loreto filed his First Amended Complaint (Doc. 7) on February 4, 2010, and Plaintiff Buffa filed his original Complaint (Doc. 1, Case No. 1:10-cv-66) on that same date. On February 22, 2010, P&G filed its original Motion to Dismiss Plaintiff Loreto's Amended Complaint (Doc. 14). P&G's original Motion to Dismiss, in substance, asserts the exact same arguments address above. Plaintiff Loreto did not respond to P&G's original Motion to Dismiss, and, instead, moved to consolidate his action with Buffa's action and to "file a consolidated amended complaint." (Doc. 20). The Consolidated Amended Complaint (Doc. 22), filed approximately three months after P&G's original Motion to Dismiss was filed, failed to cure the pleading deficiencies outlined in P&G's motion.

Because Plaintiffs had the opportunity to amend their Complaints after having notice of P&G's position, and because such amendment failed to cure any pleading deficiencies, another amendment is not warranted.

Further, even if a more carefully drafted complaint could take Plaintiffs' claims beyond merely seeking recovery for FDCA violations, such an amendment is likely futile. Plaintiffs do not plead any actual injury, *i.e.*, there are no allegations that Plaintiffs did not receive what they bargained for when they purchased the Products. Nowhere do Plaintiffs allege that the Products were actually ineffective in treating or relieving the symptoms of Plaintiffs' cold or flu. *Arcand v. Brother Int'l Corp.*, 673 F. Supp.2d 282,

301 (D.N.J. 2009) (stating that to properly plead ascertainable loss, plaintiff must "specifically allege that what he did receive [ ] was of lesser value than what was promised" and to do so, plaintiff must typically "allege facts pertinent to their own personal experience with the product"). In the Court's view, this failure to plead an actual loss confirms that Plaintiffs seek recovery based solely on P&G's alleged violations of the FDCA.

Finally, dismissal with prejudice is proper because Plaintiffs have not sought to further amend their Complaint. Accordingly, based on the foregoing, the Complaint is dismissed with prejudice.

V. CONCLUSION

Accordingly, based on the foregoing, P&G's motion to dismiss (Doc. 29) is granted, and Plaintiffs' Complaint (Doc. 22) is **DISMISSED WITH PREJUDICE**.

IT IS SO ORDERED.

Date: September 3, 2010

Timothy S. Black
United States District Judge